K012955

OCT 2 2 2001

510(k) Summary of Safety and Effectiveness

Trade Name: Coaptite™ Tissue Marker and Coaptite™ FN Tissue Marker

Common Name: Tissue Marker

Classification Name: Implantable Tissue Marker

Official Contact: Victor M. Bowers
Director Market Development
BioForm, Inc.
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Date Prepared: 8-31-01

Intended Use

Coaptite™ Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

Product Description

Coaptite™ Tissue Marker is a sterile, nonpyrogenic, flexible, semi-solid, cohesive implant used as a single use tissue marker. The principle component of the Coaptite™ Tissue Marker is synthetic calcium hydroxylapatite, a radiopaque biomaterial with over twenty years of use in orthopedics, neurosurgery, dentistry, otolaryngology, and ophthalmology. The product is available in two particle size ranges to allow different needle sizes for percutaneous placement. Coaptite™ Tissue Marker (0008025-1 and 0008026-1) has a size range of 75-125 microns. Coaptite™ FN Tissue Marker (0008027-1 and 0008028-1) has a size range of 25-45 microns. The calcium hydroxylapatite beads are clearly visible on standard radiographs as well as CT scan, MRI, and ultrasound. The cohesive semi-solid, elastic nature of the Coaptite™ Tissue Marker is created by physical bonds formed with sodium carboxymethylcellulose (NaCMC). NaCMC has also been used safely as a biomaterial for over twenty years. Coaptite™ Tissue Marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location. There is no ferrous material used in the formulation for Coaptite™ Tissue Marker and therefore it is MRI compatible.

Substantial Equivalence

The following are predicate devices that are substantially equivalent to Coaptite™ Tissue Marker.

K001807
Durasphere Tissue Marker
Carbon Medical Technologies
1290 Hammond Road
St. Paul, MN 55110

K000060
Gel Mark Biopsy Site Marker
SenoRx, Inc.
13766 Alton Parkway, Suite 144
Irvine, CA 92618

K983400
Auto Suture Site Marker staple
United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856

Coaptite™ Tissue Marker is substantially equivalent to the Durasphere Tissue Marker (K001807) manufactured by Carbon Medical Technologies, Inc., St. Paul, MN., Gel Mark Biopsy Site Marker (K000060) manufactured by SenoRx Inc., Irvine, CA., and Auto Suture Site Marker staple (K983400) manufactured by United States Surgical Corporation, Norwalk, CT. The Federal Food and Drug Administration, following review of the 510(K) pre-marketing notifications submitted by each company, approved for manufacture and sale all three of the predicate Class II devices. The 510(K) Number for each product is provided above. All of these devices have the same indication for use as radiographis soft tissue marker.

Biocompatibility Evaluations

Coaptite™ Tissue Marker is primarily formulated from synthetic dense calcium hydroxylapaptite meeting ASTM-1185, which has a proven record of excellent biocompatibility. The gel component of Coaptite™ Tissue Marker is an aqueous formulation of USP grade pharmaceutical grade excipients (glycerin and sodium carboxymethylcellulose). These excipients have extensive use in intramuscular injections such as Cortone®, Decadron®, Kenalog®, and Dalalone®. The battery of preclinical safety studies, dog implant studies, and clinical studies have shown that Coaptite™ Tissue Marker is biocompatible when injected into various submucosal or other tissues of animals. Subjects from the clinical study by Robert Mayer, M.D. are now more than five years out from implant placement with no long term concerns.

Sterilization

Coaptite is sterilized using steam; processing is performed in-house using a validated autoclave system. Cycle parameters were validated using an overkill methodology to 10^{-6} SAL. Sterilization by the user is not required.

Pre-Clinical Tests Performed

In vitro and in vivo tests were based on Tripartite and Biocompatibility guidelines and International Organization for Standardization publication ISO10993, Biological Evaluation of Medical Devices, using historically accepted test methods of biomedical materials or United States Pharmacopoeia references. These studies were conducted under GLP guidelines.

In vivo tests were performed to address sensitization, irritation, tissue reaction during short-term implantation, systemic reactions and long term safety issues. Results identified Coaptite™ Tissue Marker as nonantigenic, a nonirritant, and nontoxic with no concerns for long term safety issues based on thirty-six month data.

Summary

In summary Coaptite™ Tissue Marker is substantialy equivalent to three predicate devices which all have the same indication for use. The components used in Coaptite™ Tissue Marker are biocompatible based on the history of their use in multiple medical devices as well as from pre-clinical and clincial experience. Coaptite™ Tissue Marker is equivalent in its application and is as safe as the predicate devices named above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2001

Mr. Victor M. Bowers
Director of Market Development
BioForm, Inc.
4133 Courtney Road, #10
Franksville, Wisconsin 53126

Re: K012955
Trade/Device Name: Coaptite™ Tissue Marker and Coaptite™ FN Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Codes: NEU, GDW
Dated: August 31, 2001
Received: September 04, 2001

Dear Mr. Bowers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012955

Device Name: Coaptite™ Tissue Marker

Indications For Use:

Coaptite™ Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012955

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)